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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/089,871	06/04/1998	RUDOLF CAROLUS MARIA BARENDSE	251502008600	3289

25225 7590 07/27/2007
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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
07/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/089,871	BARENDSE ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,19,21-24,26-28,31-35,41-48 and 50-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19,21-24,26-28,31-35,41-48 and 50-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 18-19, 21-24, 26-28, 31-35, 41-48 and 50-52 are pending.

Applicant's amendment of claims 18-19 as submitted in a communication filed on 6/18/2007 is acknowledged.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/18/2007 has been entered.

Claims 18-19, 21-24, 26-28, 31-35, 41-48 and 50-52 are at issue and are being examined herein.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

1. Claim 18 is objected to because of the recitation of "prepared by extrusion". This term has been recited twice when describing the method of preparing the granulate. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 18-19, 21-24, 26-28, 31-35, 41-48 and 50-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claims 18-19 (claims 21-24, 26-28, 31-35, 41-48 and 50-52 dependent thereon) are indefinite in the recitation of "increased pelleting stability" for the following reasons. First, the term is unclear and confusing in the absence of a basis for comparison (i.e., increased with respect to what). In addition, one of skill in the art would interpret the term "pelleting stability" to refer to the structural stability of the pellet under different conditions (e.g., temperature, pressure, pH, etc.). The specification does not explicitly defines the term. It appears from Applicant's response and Example 5 of the specification that "pelleting stability" is related to the phytase activity in the pellet and not to the structural stability of the pellet. However, it is unclear from Example 5 how is pelleting stability related to phytase activity. While Table 2 refers to "enzyme yield after pelleting", it is not possible to determine what this yield is or how it is calculated. Is it related to how much enzymatic activity is left in the pellet after pelleting? If this is the case, what is the reference point for comparison? Also, how does the calculation of enzyme yield take into account dilution of enzyme due to the addition of feed premix to the granulate to make the pellets?. In the absence of any information as to what is the intended meaning of "pelleting stability", one cannot determine the entire scope of the claims or whether a teaching of the prior art meets the recited limitation. For examination purposes, no patentable weight will be given to the term. Correction/clarification is required.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 18-19, 21, 24, 26-28, 31-35, 41-45, 48, 50-52 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996).

7. Claims 22-23, 46-47 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) as applied to claims 18-19, 21, 24, 26-28, 31-35, 41-45, 48, 50-52 above, and further in view of Markussen et al. (U.S. Patent No. 4106991, 1978).

8. Claims 18-19, 21-22, 24, 26-28, 31-35, 41-46, 48, 50-52 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996), and further in view of Haarasilta (GB 2-139868A, 1984).

9. Claim 23 and 47 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) and Haarasilta (GB 2-139868A, 1984) as applied to claims 22 and 46, and further in view of Markussen et al. (U.S. Patent No. 4106991, 1978).

10. These rejections have been discussed at length in previous Office actions and they are maintained for the reasons of record in view of the fact that the limitation "high activity phytase-containing granulate" now recited in claims 18-19 has not been given patentable weight as the claims already recite how much phytase activity is required in the granulate (i.e., at least 6000 FTU/gram). Since the phytase activity has been numerically defined, the term "high activity phytase-containing granulate" is deemed redundant. Also, the limitation "increased pelleting stability" has not been given patentable weight for the reasons extensively discussed above.

11. Applicant argues that evidence of an unobvious or unexpected advantageous property can rebut prima facie obviousness citing MPEP 716.02(a). Applicant submits that none of the cited references teach or suggest an extruded high activity phytase-containing granulate having increased pelleting stability using starch as the non-fibrous carrier. Applicant also refers to Examples 5 and 10 as evidence of the increased pelleting stability achieved using Applicant's granulate.

12. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the instant rejections. For the reasons extensively discussed in prior Office actions, the combined teachings of Nielsen, Ghani, Markussen and Haarasilta do render the claimed invention obvious over the prior art.

Nielsen discloses every single aspect of the granulate/composition claimed except for (a) the carrier comprising at least 15% w/w of starch and the presence of a divalent cation (claims 18-19, 24, 26-28, 31-35, 41-44, 48, 50-52), and (b) the presence of a derivatised cellulose/edible oil/water insoluble compound (claims 21-23, 45-47). Nielsen teaches an *Aspergillus* phytase-containing granulate comprising 10,000 FTU/gram of total composition (page 5, lines 25-29; page 10, lines 16-21; page 11, lines 27-30; page 12, lines 18-21). Nielsen teaches that the phytase is derived from several strains of *Aspergillus* such as *niger* and *ficcum* (page 7, lines 4-6). Furthermore, Nielsen teaches a phytase-containing feed additive comprising additional glucosidase enzymes such as xylan-endo-1,3-β-xylosidase and endo-1,6-β-glucanase (page 11, lines 5-19). Nielsen teaches that the phytase granulate can be used as an additive for animal feed (page 10, lines 16-21). Ghani provides an enzyme granulate wherein the solid carrier is a starch-containing compound including a carrier containing 90% (w/w) of soy flour and 10% corn syrup. Haarasilta provides a granulate comprising soy oil and teach that the addition of calcium cations (divalent cation) in inorganic salts aid in the formation of stable granules (page 2, line 21). Markussen provides enzyme granules comprising PVA and CMC. Thus, contrary to Applicant's assertions, the claimed invention is prima facie obvious over the teachings of the prior art.

It is noted that the limitation regarding extrusion is a "product-by process" limitation. It is settled case law that the patentability of a product recited in product-by-process format is determined only by the characteristics of the product (see MPEP § 2113). In addition, as indicated above, limitations regarding pelleting stability have not been given patentable weight as it is completely unclear what is the intended meaning of the term "pelleting stability" or how it should be interpreted. The Examiner has carefully review the specification, specifically Examples 5 and 10, to determine the intended meaning of the term

and how a conclusion regarding pelleting stability was reached. However, for the reasons extensively discussed above, the Examiner has been unable to determine what is the intended meaning of the term. It is also noted that the information provided in Example 10 is extremely unclear and confusing. For example, on page 21, lines 18-20, the specification states that feeds having three different phytase activities were obtained with granulates comprising three different phytase activities. On page 22, line 23, the activity of the three feeds is numerically different, no units are provided, and there is no indication as to the conditions which lead to these new values for activity. Thus, it is not possible to interpret Applicant's results. The limitation "high activity" has not been given any patentable weight as it is redundant since the claim already has numerically defined the amount of activity required in the granulate (i.e., at least 6000 FTU per gram). Thus, for the reasons of record, the claimed invention is deemed obvious over the teachings of Nielsen, Ghani, Markussen and Haarasilta.

13. Applicant further criticizes (1) Nielsen as failing to teach or suggest an increase in pelleting stability, and extrusion as the method to make the granulate, (2) Ghani as failing to cure the deficiencies of Nielsen, to teach the use of solely a non-fibrous carrier in a high activity phytase, and to teach an extruded granulate, (3) Markussen as failing to cure the deficiencies of Nielsen or Ghani, and instead teaching that cellulose is responsible for one the advantageous properties of the disclosed granulate (absence of an unwanted layer of starting material on the walls of the granulator), and (4) Haarasilta as failing to cure the deficiencies of Nielsen, Ghani or Markussen, and instead teaching extrusion of foodstuffs comprising fibrous components.

14. The Examiner acknowledges that (1) neither Nielsen, Ghani, Markussen, or Haarasilta discuss pelleting stability with regard to phytase granulates, and (2) Nielsen does not teach extrusion as the method for making the granulate. However, (1) a limitation regarding extrusion has not been given patentable weight since the patentability of the product is determined based on the characteristics of that product, and (2) even if one were to consider "extrusion" as a limitation, the Examiner has provided the

teachings of Haarasilta which provide granules made by extrusion. With regard to pelleting stability, for the reasons extensively discussed above, this limitation has not been given any patentable weight. It is noted however that even if this term were to be given patentable weight, it is noted that this additional limitation would be considered inherent to a phytase granulate having at least 6000 FTU/gram. Applicant has argued that it is the high phytase activity of the granulate which results in increased pelleting stability. Applicant has not argued that this effect is limited to only certain phytases, and the claims do not limit the genus of phytases in the granulate/composition claimed. Thus, based on Applicant's arguments, this effect should be seen in any phytase granulate wherein the phytase activity is at least 6000 FTU/gram. Since the granulate/composition of Nielsen, Ghani, Markussen and Haarasilta comprises a phytase activity of at least 6000 FTU/gram, this limitation is also met.

With regard to arguments that none of the references cited teach/suggest a non-fibrous carrier, while it is agreed that the references cited do not teach or suggest a carrier completely and entirely devoid of fibers, the term "non-fibrous" as used in the claims has to be interpreted as "having some fiber" in light of the teachings of the specification and those of the art. Applicant is reminded that all the examples provided use either potato, rice or corn starch. None of the examples provided in the specification use a carrier that is completely devoid of fibers. As indicated in the Advisory Action mailed on 8/15/2006, starch contains some dietary fiber (see attachment included with the Advisory action of 8/15/2006). In addition, Applicant is reminded that some of the claims are directed to a granulate which comprises a derivatised cellulose, which would add fibers to the granulate. Clearly, a granulate comprising some fibers is a preferred embodiment. Thus, in view of the teachings of the specification, the claims, and the teachings of the art, the limitation "non-fibrous" as used in the claims cannot be interpreted as "completely lacking fiber".

With regard to arguments that Markussen cannot be properly combined with the cited references because it would impermissibly change the principle of operation of Markussen's invention, it its noted

that Markussen does not teach that large amounts of cellulose are required for preparing the granulate described. If a small amount of cellulose is sufficient to improve manufacture of the granulate, one of skill in the art still would have been motivated to use a carrier with some fibers and further add a derivatised cellulose, sufficient to improve the process of granulation. Thus, contrary to Applicant's assertions, the teachings of Markussen can be combined with the teachings of Nielsen, Ghani and Haarasilta.

15. Applicant also points out that the Office has not provided a rationale for discounting the teachings of the references cited in the rejections. Applicant refers to Markussen as describing how difficult it is to achieve granulation of enzymes. Applicant argues that the Examiner has not provided a rationale for why a skilled artisan would forego the use of a fibrous carrier in an enzyme granulate particularly in view of the teachings that such a carrier is required.

16. The Examiner disagrees with Applicant's contention that the Examiner has discounted the teachings of the references cited in the rejections. .It is reiterated herein that while none of the references disclosing granulates teach carriers which are absolutely devoid of fibers, none of the references cited teach away from using a carrier with some or little fiber, which is the limitation to be met. For the reasons extensively discussed above, the claims in light of the specification and the art, do not require a granulate completely lacking fibers. All the claims require starch, which is known to have some fibers. Other claims require derivatised cellulose in addition to starch, which would add fibers to the granulate. It is the Examiner's position that one of skill in the art can be motivated to make granulates with little/some fibers as opposed to a substantial amount of fibers to avoid mechanical malfunctions in the extruder and to produce smaller granules. These motivations are not deemed contrary to the teachings of the references cited because none of these references teach that (1) large amounts of fibers are highly desirable, (2) no mechanical malfunctions are expected when large amounts of fibers are used, or (3) small granules are undesirable in any circumstance. While Markussen teaches that granulation of

enzymes is a difficult task, it is noted that Markussen does not teach the impossibility of making enzyme granules with carriers having some fiber as opposed to large amounts of fibers, nor does it teach that carriers containing soy flour and corn syrup as taught by Ghani are undesirable or cannot be used to create enzyme granulates. Thus, contrary to Applicant's assertions, the Examiner has provided a rationale which is not contrary to the teachings of the cited references.

Conclusion

17. No claim is in condition for allowance.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Primary Patent Examiner
Art Unit 1652

DR
July 21, 2007